

REMARKS

Re-Affirmation of Election of Species

As requested, Applicants re-affirm the election of senna as a laxative, docusate as a stool softener and methylnaltrexone as a peripheral opioid antagonist.

Provisional Double Patenting Rejection

The Examiner has provisionally rejected claims 48-112 and 114 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 99 and 100 of co-pending Application No. 11/441395. Applicants understand that in accordance with Section 804 of the MPEP, a “provisional” double patenting rejection will continue to be made by the Examiner until the “provisional” double patenting rejection is the only rejection remaining in one of the applications. Accordingly, Applicants will address the appropriateness of these “provisional” double patenting rejections after the Examiner withdraws all other reasons for rejection.

Claim Rejections 35 U.S.C. §112, second paragraph

The Examiner rejected claim 41 under 35 U.S.C. §112 as being indefinite because the term “needleless injection” is allegedly confusing. Applicants respectfully request reconsideration of Examiner’s rejection of claim 41.

The term “needleless injection” is a term well known in the art, and in the instant application the term is used consistent with its common meaning. The term means an injection with out a needle. A search of the USPTO databases indicates that there are over 300 issued patents that use the term “needleless injection”. A search of the internet using the term “needleless injection” reveals that the term is commonly used by companies that market such products.

It is requested that the rejection of claim 41 be withdrawn.

Claim Rejections 35 U.S.C. §103(a)

The Examiner rejected claims 1-112 and 114 under 35 U.S.C. §103(a) as being unpatentable over Pappagallo, M., The American Journal of Surgery, in view of Yuan et al., Anesthesia and Analgesia, Foss et al., Anesthesia and Analgesia, and Cooper et al, US Pat. No. 6, 455,537.

Applicant respectfully traverses.

The instant claims are directed to methods, preparations and kits for the treatment of conditions such as constipation, including a combination of a peripheral opioid antagonist and a laxative and/or a stool softener.

Pappagallo teaches various strategies for the management of opioid bowel dysfunction including a combination therapy of senna and docusate for the treatment of constipation associated with opioid bowel dysfunction. In the cases where such a regime is ineffective, Pappagallo describes the experimental use of peripheral opioid antagonists as potential therapeutic candidates to treat opioid bowel dysfunction as a replacement for conventional laxative therapy. Pappagallo does not teach a combination therapy of a laxative and/or a stool softener and a peripheral opioid antagonist. As stated "...[P]atients who do not adequately respond to treatment with a softening agent and/or stimulant may benefit from a trial of another type of laxative...(page 15S).

It is notable that Pappagallo does not suggest such a combination. Pappagallo surveys the various treatments for opioid bowel dysfunction, but Pappagallo neither cites a prior art treatment nor suggests a novel treatment that would involve the combination of a laxative and/or a stool softener together with a peripheral opioid antagonist. Instead, Pappagallo teaches and suggests that which is outlined in the background of the present invention at page 1, lines 32 and 33, that is, peripheral opioid antagonist therapy of opioid bowel dysfunction as a replacement for laxative and/or stool softener therapy.

The other references cited by the Examiner, alone or in combination with Pappagallo, do not teach or suggest a combination of opioid antagonists and laxatives/stool softeners. Yuan, Foss and Cooper were cited to teach different modes/doses of administration of opioid antagonists. None of these references supply the elements of the claims missing from Pappagallo.

In summary, Applicants submit that the pending claims directed to pharmaceutical preparations and uses of combinations of a peripheral opioid antagonist and a laxative and/or stool softener are nonobvious in view of the combined teachings of Pappagallo, Yuan, Foss and Cooper. Applicants request that the rejection on the basis of obviousness be withdrawn.

CONCLUSION

Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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